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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/076,631	02/19/2002	Paul Habermann	02481.1775	2601

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EXAMINER	
MONDESI, ROBERT B	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,631	HABERMANN, PAUL	
	Examiner	Art Unit	
	Robert B. Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *May 19, 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-12 and 21-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-12 and 21-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office action is in response to the amendment filed May 19, 2006. **Claims 1-3, 6-12 and 21-26** are presently pending and under examination.

Information Disclosure Statement

The IDS filed May 19, 2006 has been received and is signed and considered, a copy of the PTO 1449 is attached to the following document.

Withdrawal of Objections and Rejections

The objections and rejections not explicitly restated below are withdrawn.

Maintenance of rejections

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-3 and 6-12 remain rejected and **claims 21-26** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **Claims 21-26** are newly added dependent claims that do not remedy the deficiencies of the independent claims that they are dependent therefrom.

Claims 1-3 and 6-12 remain rejected **claims 21-26** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence prepared as described in Examples 1-3 of the specification and having

the signal sequences as set forth at pages 17-18 of the specification, does not reasonably provide enablement for all the possible nucleic acid molecules suggested by the general formula of claim 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use and make the invention commensurate in scope with these claims.

Claims 21-26 are newly added dependent claims that do not remedy the deficiencies of the independent claims that they are dependent therefrom.

Claim 1 remains provisionally rejected under the judicial created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of US non-provisional application 10/076,634 (1634 Application).

The above rejections were explained in the Office action.

Response to applicants' arguments

In regards to the rejection of claims under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, applicants assert that the Office action does not provide any rationale why even one species of signal sequence is necessary for the written description requirement, let alone a recitation of all examples known. The three examples cited in the Office action are more than sufficient to be representative of all species of signal sequence.

Applicants' arguments have not been found persuasive. Presently the claims are drawn to a genus of nucleic acid molecules with substantial variation and when there is substantial variation within the genus, as is the instant case, one must describe a

sufficient variety of species to reflect the variation within the genus. The specification discloses only three species of the genus of claimed nucleic acid sequences, i.e., the nucleic acid sequences obtained in Examples 1-3 of the instant specification (see pages 14-22 of the instant specification). While it is noted that the specification describes the structures of additional representative species of signal sequences (represented by Sx in claim 1) at pages 17-18, the specification fails to describe any additional representative species of the claimed genus of nucleic acid sequences, which encompasses species that are widely variant in structure. As such, the disclosure of the three representative species of nucleic acid sequences is insufficient to be representative of the attributes and features of all species encompassed by the recited genus of nucleic acid sequences.

In regards to the rejection of the claims under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid sequence prepared as described in Examples 1-3 of the specification and having the signal sequences as set forth at pages 17-18 of the specification, does not reasonably provide enablement for all the possible nucleic acid molecules suggested by the general formula of claim 1, applicants assert that the skilled artisan requires no undue experimentation to practice the invention as claimed. For example, even with multiple amino acid substitutions the skilled artisan is capable of recognizing conservative vs. radical substitution and the expected degree of effect of each. Furthermore, Applicants respectfully assert that the specification is not required to disclose all related art. The skilled artisan is expected to possess skills, such as reading a disclosure of a signal sequence and judging whether

to use that signal sequence, for example to practice the presently claimed invention. Thus all signal sequences are enabled, either by disclosure in the application or disclosure in literature or the art.

Applicants also assert that the invention as claimed is not directed to screening for proteins having "any function". The claimed invention features a nucleic acid construct that improves active yield of pure pharmaceutically relevant proteins. The structure of the nucleic acid of claim 1 includes a portion "Y" that is more efficiently expressed when used in the context of the present invention. The skilled artisan requires no undue experimentation to select a pharmaceutically relevant protein and to incorporate the relevant nucleic acid sequence in the nucleic acid of the present invention. Selection of a pharmaceutically active protein is within the skill of the art requiring no undue experimentation; selecting a nucleic acid encoding the protein requires no undue experimentation; constructing a nucleic acid according to the claimed invention that includes the selected nucleic acid encoding the protein likewise is accomplished without undue experimentation. No undue experimentation is required at any stage of use of the present invention. Thus enablement is not an issue.

Applicants' arguments have not been found persuasive. The issue in this case is the breath of the claims in light of the predictability of the art as determined by the number of working examples, the skill level of the artisan and the guidance presented in the instant specification and the prior art of record. The Applicants make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "... scope of claims must bear a reasonable

correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...". Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQZd at 1404 (Fed. Cir. 1988). Therefore, for the instant specification to be enabling, it needs to provide direction/guidance regarding an acceptable number of different nucleic acid molecules.

Absent sufficient guidance/direction one of skill in the art would not be able to practice the claimed invention commensurate in scope with the claims. Thus, for all these reasons, the specification is not considered to be enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims, the lack of guidance and insufficient working examples provided in the specification and the high degree of unpredictability as evidenced by the state of the prior art, attempting to test all the different type nucleic acid molecule encompassed by the claimed invention would constitute undue experimentation. Therefore, applicants have not provided sufficient guidance to enable one of skill in the art to make and use the claimed invention in a manner that reasonably correlates with the scope of the claims, to be considered enabling.

In regards to the provisional rejection of **claim 1** under the judicial created doctrine of obviousness-type double patenting as being unpatentable over claim 4 of US non- provisional application 10/076,634 (1634 Application) applicants have stated that

appropriate action will be taken if and when indication of allowable claimed subject matter requires amendment or other action in the conflicting application.

Conclusion

No claims are allowed

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JON WEBER
SUPERVISORY PATENT EXAMINER

Robert B. Mondesi
Patent Examiner
Group 1653

Robert B. Mondesi
7-17-06